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K963041

Heelbo, Inc.
Life Jacket with Crotch Support**510(k) Summary****1. 1. Submitter's name, Address and Contact Person****Submitter**Heelbo, Inc.
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Chicago, IL 60651**Contact Person**Joseph S. Tokarz, Manager, Regulatory Affairs
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Date Summary Prepared - October 30, 1996

2. Name of Device:

Heelbo Life Jacket with Crotch Support

3. Name of Predicate Device(s)

Heelbo Life Jacket with Crotch Support

4. Description of Device

The Heelbo Life Jacket with Crotch Support is a poncho-style safety vest with padded crotch support. The vest has three sets of two straps that are secured to various components of a wheelchair or geriatric chair to support the upper torso. When all the straps are connected per the instructions the Heelbo Life Jacket with Crotch Support is intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair.

The Life Jacket with Crotch Support is available in a polyester and cotton blend (9400) or a polyester mesh material (9400B). The following chart shows product availability:

Stock Number	Size of Vest	Color
9400	x-small	White
9400	small	Yellow
9400	medium	Blue
9400	large	Green
9400	x-large	Beige
9400B	x-small	White bias on white breezewear
9400B	small	Yellow bias on white breezewear
9400B	medium	Blue bias on white breezewear
9400B	large	Green bias on white breezewear
9400B	x-large	Beige bias on white breezewear

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Heelbo, Inc. Life Jacket with Crotch Support

5. Statement of Intended Use

The Heelbo Life Jacket with Crotch Support is intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair.

6. Statement of Technological Characteristics of the Device

The Heelbo Life Jacket with Crotch Support is a poncho-style safety vest with padded crotch support. The vest has three sets of two straps that are secured to various components of a wheelchair or geriatric chair to support the upper torso. When all the straps are connected per the instructions the Heelbo Life Jacket with Crotch Support is intended to help prevent a patient from slumping or sliding forward while seated in a wheelchair or geriatric chair.

The subject devices are identical in intended use, design, materials, manufacturing process, physical and mechanical specifications and issues of safety and effectiveness to the devices prior to the submission of this notification. The only difference is that the product labeling has been revised to comply with the Agency's labeling requirements set forth in the draft Guidance on the Content of Premarket Notification [510(k)] Submissions for Protective Restraints dated December 1995.

7. Biocompatibility Assessment

The subject devices are identical in components materials to the predicate devices. The suppliers of the materials used in the fabrication of these devices have stated that there is a history of safe use of their materials in the clothing and garment industry. In addition, Heelbo, Inc., is not aware of any reports or complaints of skin irritation associated with these materials.

8. Conclusion

Based upon the information presented above it is concluded that the proposed Heelbo Life Jacket with Crotch Support is safe and effective for its intended use and is substantially equivalent to the predicate device.